Medication Guide

Hydrocodone Bitartrate (hye" droe koe' done bye tar' trate) and Acetaminophen (a seet" a min' oh fen) Tablets, CII

Hydrocodone Bitartrate and Acetaminophen Tablets are:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage pain severe enough to require an opioid pain medicine, when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
- An opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.

Important information about Hydrocodone Bitartrate and Acetaminophen Tablets:

- **Get emergency help or call 911 right away if you take too much Hydrocodone Bitartrate and Acetaminophen Tablets (overdose).** When you first start taking Hydrocodone Bitartrate and Acetaminophen Tablets, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur. Ask your healthcare provider about medicines like naloxone or nalmefene that can be used in an emergency to reverse an opioid overdose.
- Taking Hydrocodone Bitartrate and Acetaminophen Tablets with other opioid medicines, benzodiazepines, gabapentinoids (gabapentin or pregabalin), alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.
- Never give anyone else your Hydrocodone Bitartrate and Acetaminophen Tablets. They could die from taking it. Selling or giving away Hydrocodone Bitartrate and Acetaminophen Tablets are against the law.
- Store Hydrocodone Bitartrate and Acetaminophen Tablets securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

Do not take Hydrocodone Bitartrate and Acetaminophen Tablets if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.
- known hypersensitivity to hydrocodone or acetaminophen, or any ingredient in hydrocodone and acetaminophen tablets.

Before taking Hydrocodone Bitartrate and Acetaminophen Tablets, tell your healthcare provider if you have a history of:

- head injury, seizures
- problems urinating
- liver, kidney, thyroid problems
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, opioid overdose, or mental health problems.

Tell your healthcare provider if you:

- Noticing your pain getting worse. If your pain gets worse after you take Hydrocodone Bitartrate and Acetaminophen Tablets, do not take more of Hydrocodone Bitartrate and Acetaminophen Tablets without first talking to your healthcare provider. Talk to your healthcare provider if the pain that you have increases, if you feel more sensitive to pain, or if you have new pain after taking Hydrocodone Bitartrate and Acetaminophen Tablets.
- **are pregnant or planning to become pregnant.** Use of Hydrocodone Bitartrate and Acetaminophen Tablets for an extended period of time during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breastfeeding.** Hydrocodone bitartrate and acetaminophen passes into breast milk and may harm your baby. Carefully observe infants for increased sleepiness (more than usual), breathing difficulties, or limpness. Seek immediate medical care if you notice these signs.
- living in a household where there are small children or someone who has abused street or prescription drugs.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking Hydrocodone Bitartrate and Acetaminophen Tablets with certain other medicines can cause serious side effects that could lead to death.

When taking Hydrocodone Bitartrate and Acetaminophen Tablets:

- Do not change your dose. Take Hydrocodone Bitartrate and Acetaminophen Tablets exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- For acute (short-term) pain, you may only need to take Hydrocodone Bitartrate and Acetaminophen Tablets for a few days. You may have some Hydrocodone Bitartrate and Acetaminophen Tablets left over that you did not use. See disposal information at the bottom of this section for directions on how to safely throw away (dispose of) your unused Hydrocodone Bitartrate and Acetaminophen Tablets.
- Take your prescribed dose every four to six hours as needed for pain. Do not take more than your prescribed dose. If you miss a dose, take your next dose at your usual time.
- Call your healthcare provider if the dose you are taking does not control your pain.
- If you have been taking Hydrocodone Bitartrate and Acetaminophen Tablets regularly, do not stop taking Hydrocodone Bitartrate and Acetaminophen Tablets without talking to your healthcare provider.
- Dispose of expired, unwanted, or unused Hydrocodone Bitartrate and Acetaminophen Tablets by promptly flushing down the toilet, if a drug take-back option is not readily available. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

While taking Hydrocodone Bitartrate and Acetaminophen Tablets DO NOT:

- Drive or operate heavy machinery, until you know how Hydrocodone Bitartrate and Acetaminophen Tablets affect you. Hydrocodone Bitartrate and Acetaminophen Tablets can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol. Using products containing alcohol during treatment with Hydrocodone Bitartrate and Acetaminophen Tablets may cause you to overdose and die.

The possible side effects of Hydrocodone Bitartrate and Acetaminophen Tablets:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help or call 911 right away if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme drowsiness, light-headedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.

These are not all the possible side effects of Hydrocodone Bitartrate and Acetaminophen Tablets. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov.**

This Medication Guide has been approved by the U.S. Food and Drug Administration.

For more information call Granules Pharmaceuticals Inc., at 1-877-770-3183.

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